

**Report of the Vermont Attorney General  
on the  
Advisability of Requiring Disclosure of Free Samples  
Distributed by Manufacturers of Prescribed Products to  
Vermont Health Care Providers**

**January 15, 2010**

Prepared by  
Wendy Morgan, Chief, Public Protection Division  
Christy Mihaly, Assistant Attorney General  
AJ Van Tassel-Sweet, Investigator

## Table of Contents

The Charge.....	1
Overview.....	1
The Process.....	3
Terminology.....	3
Recent Public Reports and Recommendations on Regulation of Free Samples.....	5
Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education, and Practice.....	5
MedPAC Report to Congress.....	7
District of Columbia Department of Health Report.....	8
New Jersey Attorney General's Report.....	8
The Medical and Scientific Literature.....	9
AAMC Symposium on the Scientific Basis of Influence and Reciprocity.....	10
Current Restrictions on Distribution of Samples in Vermont.....	12
Federal Law on Free Samples.....	12
Vermont Law on Free Samples.....	12
Other Restrictions.....	13
Current Practices Regarding Free Samples Nationwide and in Vermont.....	13
The National Context.....	13
Commentary Received and Current Practices in Vermont.....	14
Federal Health Care Reform Bills.....	16
Questions for Legislative Consideration, the Attorney General's Recommendations, and Commentary.....	17
Question 1: Should the distribution of free samples be reported to the Vermont Attorney General?.....	17
Question 2: Should reports of free samples made to the Attorney General be available to researchers?.....	20
Question 3: Should reports regarding distribution of free samples be released to the public?.....	21
Question 4: If free samples are disclosed, how should they be valued, if at all?.....	22
Question 5: Should only free samples be reported to the Attorney General, or should free drug products, starter packs, and/or generics also be reported?.....	23
Issues Not addressed in the Report and Recommendations.....	25

# **Report of the Vermont Attorney General on the Advisability of Requiring Disclosure of Free Samples Distributed by Manufacturers of Prescribed Products to Vermont Health Care Providers**

## **The Charge**

The Vermont Legislature, in an Act Relating to the Marketing of Prescribed Products, charged the Attorney General to “conduct a review, in consultation with the commission on health care reform, of the advisability of modifying section 4632 of Title 18 to require the disclosure of information about the provision of samples to health care providers by manufacturers of prescribed products.” (Act 59, Sec. 5a (2009)) This report is submitted to the Legislature in response to this charge. Its discussion and recommendations focus on issues related to the potential reporting of free samples; it does not reach the larger question – on which some comments were received – of the advisability of other limitations, or a complete prohibition, on the distribution of free samples.

## **Overview**

This report reviews recent public reports and recommendations on the regulation of free samples from the Institute of Medicine, the Medicare Payment Advisory Commission, the District of Columbia, and the New Jersey Attorney General. It then briefly describes a number of studies on the effects of free samples on prescribing patterns, and summarizes presentations on the neuroscience, psychological, and behavioral economic perspectives on influence and reciprocity from a recent conference sponsored by the Association of American Medical Colleges and Baylor College of Medicine.

Federal and Vermont laws on free samples, as well as other restrictions, are set forth, as well as a brief description of current practices regarding free samples nationwide and in Vermont.

Input from stakeholders, received in the form of testimony at a public hearing and written submissions, is incorporated throughout, primarily in connection with the five questions presented in the final section of the report. Those questions and the Attorney General’s recommendations are as follows.

### *Question 1:*

*Should the distribution of free samples be reported to the Vermont Attorney General?*

Recommendation: The distribution of free samples of drugs and medical devices should be reported to the Attorney General on an annual basis, with the timing and definitions consistent with federal regulation to the extent that that is possible while maintaining the intent of the Vermont Legislature.

*Question 2:*

*Should reports of free samples made to the Attorney General be available to researchers?*

Recommendation: If the Legislature acts to require data on the distribution of free samples to be reported to the Attorney General, the Attorney General should be authorized to release the data to academic researchers for analysis and public reporting, consistent with the confidential nature of the reporting, if any.

*Question 3:*

*Should reports regarding distribution of free samples be released to the public?*

Recommendation: At this time, any public release of disclosures of the distribution of free samples should not include identification of individual recipients.

*Question 4:*

*If free samples are disclosed, how should they be valued, if at all?*

Recommendation: Any reporting to the Attorney General should include the identity, dosage, and number of units of each free sample, and the recipient's identity. If the Legislature envisions any public disclosure of the data – whether aggregated or not – then a value should be associated with free samples; if the Legislature envisions simply that the data be made available to researchers, then a value is not necessary.

*Question 5:*

*Should only free samples be reported to the Attorney General, or should free drug products, starter packs, and/or generics also be reported?*

Recommendation: The distribution of generic products, if there is any by manufacturers, should not be required to be reported to the Attorney General. The Attorney General takes no position on the question of whether free drug product or starter packs should be reported.

The report does not address a number of arguments that emerged during the public hearing process, but does identify them in case the Legislature desires to address them: a ban on free samples, other interventions to reduce detrimental effects of samples, free samples as gifts, consistency with federal law, prescriptions in Vermont prisons, disclosure requirements for health care providers, and the cost of brand name drugs.

## The Process

The Vermont Attorney General held a public hearing on October 27, 2009, to take public testimony on the advisability of requiring disclosure of free samples. The hearing lasted over two hours and was attended by 64 people in person, with about 15 more participating by conference call. Sixteen people testified: industry representatives, academicians, patient advocates, and members of the general public. Stakeholders were asked to submit written comments by November 6, 2009.<sup>1</sup> The Attorney General's Office also conducted additional inquiries and analysis in preparing this report.

## Terminology

As used in this report, the following terms have the meanings set forth below.

**“Drugs”** refers to both prescribed chemical substances and biological products (or “biologics”) intended for use in the medical diagnosis, cure, treatment, or prevention of disease in humans.<sup>2</sup> Examples of drugs that are chemical substances include Exelon, Lantus, Lexapro, Lipitor, and Strattera; whereas biologics (derived from living material) include blood and its components and derivatives when used for transfusion, vaccines, treatments such as Enbrel (a biologic treatment for rheumatoid arthritis and plaque psoriasis), as well as Erbitux and other cancer drugs.

**“Medical device”** as used in Act 59 refers to the federal definition. This definition includes equipment requiring a prescription, non-prescribed devices ranging from catheters and surgical tools to artificial knees and hips, as well as large laboratory equipment and diagnostic imaging devices. As used in this report, “medical device” also includes a medical device combined with a drug. For example, a stent is a medical device used to keep an artery open; a stent that releases drugs is a combination medical device and drug which falls within the definition of “medical device” for purposes of this report.<sup>3</sup>

---

<sup>1</sup> In citations to information provided to the Attorney General's Office, written submissions are identified by the company or other person or entity that submitted the materials; statements provided at the public hearing are identified by the name of the person who testified. Written submissions (whether by letter or email) and oral testimony from the public hearing are available on the Attorney General's website.

<sup>2</sup> Under federal statutory law as incorporated into 18 V.S.A. § 4631a(a)(10), “drug” is defined separately from a biological product. 21 U.S.C. § 321, 42 U.S.C. § 262. For some federal regulatory purposes, “drug” is treated as including biologics. E.g., 21 C.F.R. § 203.3(y) (“drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices).”) To simplify here, we define “drug” for purposes of this report to include both chemical substances and biologics.

<sup>3</sup> To complicate matters, combination devices may or may not be regulated by the FDA as medical devices. In addition, a medical device may or may not be a medical supply item in another context, such as insurance coverage. As far as we know, medical device companies do not provide free samples of any medical supplies that fall outside the definition of a “medical device.” (AdvaMed(2))

**“Free sample”** means a sample of a drug or medical device that is provided free of charge to a health care provider in order to promote the marketing of the drug or device.<sup>4</sup>

A “drug sample,” according to the Food and Drug Administration (FDA), is a unit of a drug “which is not intended to be sold and is intended to promote the sale of the drug.” 21 U.S.C. § 353(c)(1). The FDA has stated that such “samples” do not include (1) drugs provided free of charge to physicians for their indigent patients, 64 Fed. Reg. 67720, 67743 (Dec. 3, 1999), i.e. what we define as “free drug product” for this report; or (2) “starter packs,” i.e. packets of drugs given free of charge to a pharmacist for sale to a consumer, 59 Fed. Reg. 11842, 11855 (Mar. 14, 1994).

The FDA does not have a definition of a medical device sample. The medical device industry has three types of product samples: (1) direct to patient single-use disposable devices such as advanced wound care bandages and catheters, both of which may be devices or a combination device and drug; (2) demonstration devices, such as artificial joints, used when preparing a patient for surgery; and (3) evaluation units provided to a practitioner to evaluate the equipment for their practice. (Advanced Medical Technology Association (AdvaMed), representing 1300 medical device companies; AdvaMed(2)) As noted below on page 12, the last two categories are already addressed in Vermont law.

**“Free drug product:”** Some health care providers, particularly free clinics, receive free drug products, as distinct from “free samples.” These free drug products are generally older products not presently being marketed by a manufacturer, which are given to the clinics for distribution to patients.

---

<sup>4</sup> For purposes of Vermont law on gifts by manufacturers of prescribed products, a “health care provider” is “a health care professional, a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescribed products in this state.” 18 VSA § 4631a(a)(6). A “health care professional” is defined in 18 VSA § 4631a(a)(5)(A) as “(i) a person who is authorized to prescribe or to recommend prescribed products and who either is licensed by this state to provide or is otherwise lawfully providing health care in this state; or (ii) a partnership or corporation made up of the persons described in subdivision (i) of this subdivision (5)(A); or (iii) an officer, employee, agent, or contractor of a person described in subdivision (i) of this subdivision (5)(A) who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals.”

## Recent Public Reports and Recommendations on Regulation of Free Samples

The distribution of free samples by manufacturers of prescribed products has been a topic of concern in recent analyses of medical cost containment, and in discussions of conflicts of interest arising from relationships between prescribers and manufacturers or distributors. Given that disclosure of the distribution of free samples is generally not required, we are not aware of any studies on the effects of such disclosure per se.<sup>5</sup> Further, very little data has been collected regarding marketing or free samples of medical devices.<sup>6</sup> This section summarizes several recently published reports that address the potential regulation of free samples.

### *Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education, and Practice*

The Institute of Medicine, in April 2009, published a comprehensive report examining conflicts of interest in medical research, education, and practice. It formulated a series of recommendations to address and avoid such conflicts of interest, including three recommendations relevant to the treatment of free samples (drug samples only).

*Recommendation 5.1.* For all faculty, students, residents, and fellows and for all associated training sites, academic medical centers and teaching hospitals should adopt and implement policies that prohibit . . . the use of drug samples, except in specified situations for patients who lack financial access to medications.

*Recommendation 6.1.* Physicians, wherever their site of clinical practice, should . . . not accept drug samples except in certain situations for patients who lack financial access to medications.

*Recommendation 6.2.* Pharmaceutical, medical device, and biotechnology companies and their company foundations should have policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or similar items of material value . . . .

B. Lo and M. Field, eds.; Institute of Medicine of the National Academies, Committee on Conflict of Interest in Medical Research, Education, and Practice, Board on Health Sciences Policy, *Conflict of Interest in Medical Research, Education and Practice*, April 21, 2009, at 19-20.

---

<sup>5</sup> State-level pharmaceutical marketing disclosure requirements in Maine, Massachusetts, Minnesota, West Virginia, and the District of Columbia have exempted the distribution of free samples for patients from their reporting requirements. Me. Rev. Stat. Ann. Tit. 22, § 2698-A; Mass. Gen. Laws ch. 111N, § 2; Minn. Stat. § 151.461; W. Va. Code § 5A-3C-1; D.C. Code Ann. § 48-833.03.

<sup>6</sup> “We are not aware of published studies that quantify the extent of relationships between medical device manufacturers and physicians.” *Report to the Congress: Medicare Payment Policy*, Medicare Payment Advisory Commission (MedPAC), March 2009, p. 339.

In explaining the basis for these recommendations, the Institute of Medicine report discusses several surveys regarding physicians' relationships with the pharmaceutical industry. It cites the following:

- “Surveys show that relationships with industry are common among physicians across the nation. In a national probability sample of more than 3,100 physicians, 94 percent reported that they had had some type of relationship with industry during the preceding year. These relationships were primarily the receipt of food in the workplace (83 percent) or drug samples (78 percent). (Campbell et al., 2007a)”
- “Another national survey of physicians also found that relationships with industry are common: 92 percent of physicians had received free drug samples,” . . . (KFF, 2002)”
- “A study of community obstetricians-gynecologists reported that most physicians believe that it was appropriate for physicians to accept drug samples (92 percent) . . . (Morgan et al., 2006)”
- “As was found in a number of other studies, the respondents thought that other physicians were more likely (probably or almost surely) to be influenced by receiving a drug sample than the respondents were (38 percent for other physicians versus 33 percent for the respondents).”

*Id.* at 172.

The Institute of Medicine report sets out the “Issues” and “Responses” related to the provision of free samples, and summarizes its conclusions as follows:

[T]he committee recognizes that access to affordable medications is a serious problem for many Americans, but it believes that reliance on drug samples is an unsatisfactory response. Samples are typically available only for newer and heavily marketed drugs, which may have no proven clinical benefits over alternatives, including less expensive equivalent drugs or generics. Although a sample may be convenient for the patient, it may not be the most appropriate medication. Many samples are provided to patients with insurance coverage and to physicians and their families, groups that do not have impaired access to medications. In such situations, the convenience of samples is outweighed by their potential to undermine evidence-based, cost-effective prescribing. For patients with chronic illnesses who lack the ability to pay for medications, a sample should be a stopgap that is accompanied by referral of the patient to a public or pharmaceutical company assistance program that can provide continuity of treatment. If physicians decide to accept drug samples, they should be given to patients who lack financial access to medications in situations in which appropriate generic alternatives are not available and the medication can be continued at little or no cost to the patient for as long as the patient needs it. . . . Some committee members were in favor of banning the acceptance of drug

samples altogether and advocating for other mechanisms for providing access to drugs for indigent patients.

*Id.* at 186-87; *see also* 134-36.

#### *MedPAC Report to Congress*

Analysis of the effects of free samples on prescribing practices and health care costs has been limited in part because of a lack of data about the distribution of such samples. For this reason, the Medicare Payment Advisory Commission (MedPAC) recently recommended that Congress require reporting of the distribution of free samples of drugs to the Secretary of the U.S. Department of Health and Human Services. In its March 2009 *Report to the Congress on Medicare Payment Policy*, MedPAC, citing concerns that free sampling may influence physicians' prescribing decisions and lead physicians and patients to rely on more expensive drugs when less expensive medications might be equally effective, recommended collecting more data on the distribution of free samples, and making it available to researchers to enable them to study more thoroughly the impacts of samples on prescribing patterns and costs. Medicare Payment Advisory Commission, *Report to Congress, Medicare Payment Policy*, xxi, 317-18, 332-35 (2009). The report noted that more information about the distribution of free samples would also facilitate the targeting of government or health plans' counter-detailing programs, which provide information on drugs to doctors through educational visits.<sup>7</sup> MedPAC pointed out that the pharmaceutical industry provides samples worth billions of dollars to providers each year, and that although the samples offer benefits for many patients, they may increase health care costs overall.

MedPAC recommended:

*Recommendation 5-3:* The Congress should require manufacturers and distributors of drugs to report to the Secretary the following information about drug samples:

- Each recipient's name and business address;
- The name, dosage, and number of units of each sample; and
- The date of distribution.

The Secretary should make this information available through data use agreements.

*Id.* at 335.

In other recommendations, the MedPAC advocated the public disclosure of financial relationships between manufacturers and physicians, including payments, gifts, and food.

---

<sup>7</sup> The Vermont Legislature, recognizing that counter-detailing has the potential to provide non-marketing educational information regarding medications to health care providers, has required the Department of Health to establish an "evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs." 18 V.S.A. § 4622.

For free samples, in contrast, the recommendation is to require reporting to HHS but not public disclosure, and no reporting of the value of the samples.

In discussing the implications of the reporting of free samples of drugs, MedPAC noted that although manufacturers will incur additional administrative costs, they do currently collect much of this information. It stated in addition that Medicare beneficiaries may indirectly benefit from research evaluating the impact of free samples on prescribing behavior and overall drug spending. MedPAC, like the Institute of Medicine committee, focused on prescription medications, and not medical devices.

#### *District of Columbia Department of Health Report*

A recent report by the George Washington University School of Public Health and Health Services investigated trends in pharmaceutical marketing expenditures and health care costs in the District of Columbia, based in part on data collected by the D.C. Department of Health under the District's prescription drug marketing costs reporting requirements. The report, [Impacts of Pharmaceutical Marketing on Healthcare Services in the District of Columbia \(June 15, 2009\)](#), summarized trends in marketing and advertising expenditures, targeting both physicians and consumers, nationally and in D.C. Among its conclusions was that "[p]harmaceutical marketing activities can influence the cost, utilization, and delivery of healthcare services in the District by leading to the use of expensive brand-name drugs that may be inappropriate, or even dangerous, for some patients." *Id.* at 39.

The researchers noted that, because of a lack of data, they were unable to analyze the extent or influence of the pharmaceutical companies' practices of providing free samples to health care providers, or of sponsoring clinical trials. D.C. law does not require manufacturers to report such expenditures, and the GWU report recommended that the law be amended to require reporting of both. *Id.* at 36. The report summarized published studies that indicated that access to drug samples affects prescribing patterns, and that the ultimate recipients of samples tended not to be poor or uninsured patients. *Id.* at 20. Citing concerns that the role of free samples is not primarily to assist patients who could otherwise not afford needed drugs, and that "the distribution of free samples may cause both prescribers and patients to rely on drugs that may not be the most appropriate or cost-effective options," the report concluded that researchers need access to data about free sampling, to "allow for a better understanding of the scope" of the practice. *Id.* at 20, 40.

#### *New Jersey Attorney General's Report*

The New Jersey Division of Consumer Affairs recently released its Report on Physician Compensation to the New Jersey Attorney General. The goal of the study was to identify ways to minimize conflicts of interest between physicians and pharmaceutical companies and medical device manufacturers, and "ensure that patient care is always guided by the unbiased, best judgments of the treating doctor." (Executive Summary, p. 1.) The report focused on recommendations regulating doctors' financial relationships with

manufacturers by imposing requirements on the doctors themselves; it recommended prohibiting doctors from receiving gifts, including travel expenses and meals (with limitations) from manufacturers of prescribed products, and requiring the disclosure of permissible financial arrangements.

Unlike the Institute of Medicine and MedPAC, the New Jersey Attorney General's report did not recommend limitations on, or reporting of, free samples. Although concluding that the availability of free samples affects physician prescribing, and may lead to the increased prescription of the sampled drugs and increased costs, the report cites a "consensus among physicians that the provision of sample medications benefits patients and should be continued." New Jersey Attorney General, [\*Report on Physician Compensation Arrangements\*](#), December 3, 2009, at 5-6.

## **The Medical and Scientific Literature**

In addition to the surveys described briefly in the Institute of Medicine Report, and above at page 6, the following studies on the effects of the availability of free samples on prescribing patterns were reviewed for this report.

- Physicians in a large university-affiliated internal medicine practice were three times more likely to prescribe generic medications to uninsured patients after drug samples were removed from the office. Free drug samples may lead to higher costs for uninsured patients by encouraging physicians to write prescriptions for brand-name only drugs. Two factors were associated with generic prescribing: the absence of drug samples and the prescriber being an attending physician. David P. Miller, MD, et al., *The Impact of Drug Samples on Prescribing to the Uninsured*, Southern Medical Journal, Sep 2008, at 888.
- Family physicians who distribute free samples are more likely to prescribe those medications than their counterparts who do not, are convinced they are helping patients, and do not necessarily believe that their prescribing behavior is influenced by pharmaceutical companies. Barbalee Symm PhD, RN, et al., *Effects of using Free Sample Medications on the Prescribing Practices of Family Physicians*, Journal of the American Board of Family Medicine, Sep-Oct 2006, at 443.
- Access to drug samples in a clinic influences residents' prescribing decisions. As compared to their peers, residents with access to free samples are more likely to write new prescriptions for heavily advertised drugs, and trend towards less use of inexpensive drugs. This could affect residents' education and increase costs for patients. In addition, the study quoted another study finding that physicians in practice "tend to underestimate their personal response to marketing." Richard F. Adair, MD, et al., *Do Drug Samples Influence Resident Prescribing Behavior? A Randomized Trial*, The American Journal of Medicine, Aug 2005, at 881.
- The results of a study of prescribing habits of family practice residents and faculty in the treatment of hypertension suggest that free samples affects prescribing: More "first-line" drugs [preferred drugs according to a published report of a national committee] were prescribed when free samples were prohibited than when they were

available. The article noted a 1997 study which found that only 54% of drug samples go to patients; the remainder are used by physicians, family, and staff. John M. Boltri, MD, et al., *Effect of Antihypertensive Samples on Physician Prescribing Patterns*, Family Medicine, Nov-Dec 2002, at 729.

- Physicians self-report that the availability of drug samples led them to dispense and subsequently prescribe drugs that differ from their preferred drug choice. Lisa D. Chew et al., *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, Journal of General Internal Medicine, July 2007, at 478.
- In a study of three family practice residency programs, each with a well-designed pharmacy curriculum (including “academic detailing”), and three different policies on availability of drug samples (unlimited, limited, and prohibited), residents in programs which limited or prohibited samples wrote a higher percentage of generic prescriptions than those that did not actively control samples. However, this did not lead to a decrease in the prescription costs and the overall prescribing patterns were similar. Dan Brewer, MD, *The Effect of Drug Sampling Policies on Residents' Prescribing*, Family Medicine, Jul-Aug 1998, at 482.

#### *AAMC Symposium on the Scientific Basis of Influence and Reciprocity*

In 2007, the Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit, sponsored a symposium “to explore the challenges to objectivity that are presented by gifts, favors, and influence” and the “derivation and nature of influence and reciprocity” when “the research missions of academic medicine are markedly dependent on industry support. The real or perceived biases that can result from these relationships challenge the integrity and independence of medical education, research, and patient care, as well as the public’s confidence in the trustworthiness of academic medicine.” Baylor College of Medicine, Department of Neuroscience Computational Psychiatry Unit, Association of American Medical Colleges, *The Scientific Basis of Influence and Reciprocity: A Symposium*, [www.aamc.org/publications](http://www.aamc.org/publications), June 12, 2007. In introducing the symposium report, the editors wrote:

The consistency of experimental findings from the several scientific approaches [neuroscience, psychological, behavioral economics] described by the speakers at the symposium was remarkable, as were the suggestions offered for addressing the biasing effects of influence and reciprocity on decision making and choice.

1. There are systematic and predictable ways in which people act unethically that are beyond their own awareness.
2. The more leeway honest persons have, the more likely they are, given the opportunity, to behave unethically, but only up to a point that appears to be determined by the person’s own self-concept.
3. Increasing awareness of moral standards, or mindfulness, at the time of decision making diminishes the tendency to behave unethically.
4. Self-interest unconsciously biases well-intended people, who give themselves, bounded “moral wiggle room” to engage in unethical behavior with an easy conscience.

5. Circumstances that can create conflicts of interest should be eliminated wherever possible in order to decrease temptations and likelihood to act unethically.

From the panel of responders, two key messages emerged. First, the task of convincing physicians, who are selected for their ability to reason, that they are not reliably reasonable, is not simple. Second, though people cannot exercise unlimited control of their instinctive behavior, they are capable of imposing some modifications on it. Purposeful structuring of relationships and interactions to diminish potential conflicts of interest reinforces that capability.

*Id.* at 2.

The presenter providing the neuroscience perspective, Reed Montague of Baylor College of Medicine, described how functional magnetic resonance imaging (fMRI) helps us understand the degree and to what “level of covert subtlety” gift or other favors influence behavior. In discussing one experiment, he said:

The game demonstrates the human tendency to expect – until proven wrong—that *favors given will be paid back*. In fact, the experiment suggests, but does not prove, that this process has strong automatic components that covertly influence one’s decision to trust someone else. These findings raise the question of how relatively subtle acts of benevolence may generate reciprocal behavioral responses on the part of the recipient – responses that may not reach the level of conscious intention.

*Id.* at 11 (italics in original). In response to a question about whether “experts,” presumably doctors, might be less influenced by favors, Dr. Montague responded: “Current data suggest that we are not descended from pure altruists. Even very mild favors clearly matter and have a subtle—and sometimes glaring—impact on our judgments.” *Id.* at 12.

The presenter providing the behavioral economics perspective, George Loewenstein of Carnegie Mellon University, stressed the following conclusions:

- Conflicts of interest will inevitably bias physician behavior, however honorable and well-intentioned specific physicians may be. Bias may distort their choices, or they may look for and unconsciously emphasize data that support their personal interests.
- The only viable remedy is to eliminate [conflicts of interest] whenever possible—e.g., eliminate gifts from pharmaceutical companies to physicians. This should include gifts of any size, because even small gifts can result in unconscious bias.

*Id.* at 23.

## **Current Restrictions on Distribution of Samples in Vermont**

### *Federal Law on Free Samples*

Federal law allows manufacturers of prescription drugs, and their authorized distributors, to distribute samples only if they receive a written request containing specified information, obtain an executed receipt, and maintain both for three years. 21 U.S.C. § 353(d). The samples must be labeled as such (e.g. “sample,” “not for sale,” or “professional courtesy package”), and must have a lot control number to allow for tracking. 21 C.F.R. § 203.38. Manufacturers must maintain distribution records by recipient and by lot number, conduct an annual physical inventory of distributed drug samples, reconcile the results with the most recent inventory, and notify the Food and Drug Administration (FDA) and investigate any diversion or theft of drug samples. 21 C.F.R. §§ 203.31(d), 203.34, 203.37, 203.38.

Drug samples may be provided only to licensed practitioners. Practitioners may choose to donate the samples to a charitable institution, which must maintain a donation record and conduct an annual inventory. 21 C.F.R. § 203.39.

Although the FDA does not have a definition of medical device “sample,” its approach is to review technologies falling within its medical device jurisdiction. Manufacturers can market the products only in accordance with the FDA’s clearance and approved labeling. AdvaMed’s Code of Ethics regarding sampling applies only to FDA-cleared products. (AdvaMed(2))

### *Vermont Law on Free Samples*

Effective July 1, 2009, Vermont law bans most gifts by manufacturers of prescribed products to health care providers, but expressly exempts from the ban (1) the loan of a medical device for up to 90 days to permit evaluation of the device by a health care provider or patient, and (2) the provision of demonstration or evaluation units to assess the appropriate use and function of the product and to determine whether and when to use or recommend the product in the future. 18 V.S.A. § 4631a(b)(2)(B), (C).

Vermont also excepts from its gift ban “samples of a prescribed product [pharmaceutical products, biologics, medical devices, and combinations thereof] provided to a health care provider for free distribution to patients.” 18 V.S.A. § 4631a(b)(2). Although allowable expenditures and gifts by manufacturers of prescribed products must be reported to the Attorney General, Vermont does not require reporting of “samples of a prescription drug provided to a health care professional for free distribution to patients.” 18 V.S.A. § 4632(a)(1)(A)(iv). As a result of the differences in wording between these two statutory sections, manufacturers of medical devices are required to report to the Attorney General distribution of free samples of medical devices to health care providers after January 1,

2010, though no value need be placed on the products. Under Act 59 this reporting is due by October 1, 2010.<sup>8</sup>

### *Other Restrictions*

A number of Vermont health care providers, through internal policies, prohibit acceptance of free samples of drugs. For example, according to Paul Taheri, M.D., Fletcher Allen Health Care Faculty Practice President, in October 2008, Fletcher Allen made a policy decision to stop accepting sample medications within their physician office practices. Similarly, while Dartmouth Hitchcock Medical Center has not banned the use of free samples, it has instituted policies that discourage their use. According to Frances C. Brokaw MD, MS, “the procedure required for documentation of samples received, and dispensed, is so onerous that I don’t think anyone does it anymore.”

In addition, there are undoubtedly health care professionals who have chosen independently not to accept free samples from manufacturers. The extent to which professionals have made this choice is not known. We do know from the data that forms the basis of the Attorney General’s most recent Pharmaceutical Marketing Disclosures report, that fewer than 50% of Vermont prescribers receive gifts or other expenditures from pharmaceutical manufacturers.<sup>9</sup>

Finally, manufacturers of prescribed products have their own sampling policies. (AstraZeneca; AdvaMed) In addition, AdvaMed’s Code of Ethics includes provisions addressing medically appropriate dispensing of device samples. (AdvaMed)

## **Current Practices Regarding Free Samples Nationwide and in Vermont**

### *The National Context*

According to Community Catalyst, a national non-profit consumer advocacy organization for affordable health care, 30% of the cost of prescription drugs is attributable to marketing costs, and 78% of physicians report receiving drug samples from industry, the highest percentage reported for any basis of a relationship (such as consulting, speaker, clinical trials) except for gifts – 83% of respondents reported receiving gifts.

---

<sup>8</sup> As a result of this statutory language, a question has arisen as to whether free samples of medical devices should be treated differently from free samples of drugs. AdvaMed argues that medical device manufacturers should be exempt from disclosure, as the drug manufacturers are. The Attorney General believes that without more information justifying a difference in treatment, both should be subject to parallel reporting requirements, as determined by the Legislature.

<sup>9</sup> In FY2008, there were 2,280 recipients of marketing expenditures in Vermont, more than a quarter of whom were not prescribers, at a time when there were 4,573 licensed Vermont prescribers (though an unknown number of them were on limited temporary licenses which did not allow prescribing). Vermont Attorney General’s Office, [\*Pharmaceutical Marketing Disclosures July 1, 2007 – June 30, 2008\*](#), April 2009, at 1,5.

PhRMA, an industry advocate representing pharmaceutical research and biotechnology companies, was unable to identify “any credible source of information about volume of samples distributed within any region or throughout the country.”

Materials submitted by Community Catalyst, citing a number of research studies, indicated that, of a total of \$29.88 billion spent on promoting prescription drugs in 2005, \$18.44 billion, or 61.7%, was spent on free samples. Further, the cited studies showed that less than one third of all sample recipients were low income; less than one fifth of all sample recipients were uninsured at any point during the year; and physicians, office staff, and sales reps commonly use samples intended for patients. In a comparison of 23 similar practices, physicians in clinics distributing samples had higher prescribing costs, and the prescribing patterns correlated with the samples dispensed.

In a written submission distributed at the October 2009 Vermont hearing on free samples, Richard G. Pinckney, from the Office of Primary Care at the University of Vermont, College of Medicine, provided national data on the use of free drug samples.

The pharmaceutical industry invests heavily to provide sample medications to prescribers. The retail value of medication samples distributed in the United States exceeded \$18 billion in 2005, an amount that has tripled in 10 years. These free medications reach many prescribers and patients. In 2003, 12% of all Americans received a sample medication, and in 2004, nearly half of all Medicare beneficiaries asked for or received samples. Furthermore, 92% of physicians stated that they had received samples from pharmaceutical representatives at least once in their career, according to a national representative survey.

(Pinckney, citations omitted.)<sup>10</sup>

#### *Commentary Received and Current Practices in Vermont*

The extent to which free samples are distributed in Vermont is not known. (See, e.g. PhRMA) However, given that Vermont’s population is .2 % of the U.S. population, assuming the national expenditures described above were distributed proportionally by population, Vermont health care providers received nearly \$60 million (.2% of \$29.88 billion) in promotional spending in 2005, of which nearly \$37 million (.2% of \$18.44 billion) was in free samples.

Manufacturers distribute free samples using a variety of systems. For example, AstraZeneca distributes free drug samples “through three different methods: sales

---

<sup>10</sup> Quoting similar statistics on promotional spending by the pharmaceutical industry at the 2007 AAMC Symposium on the Scientific Basis of Influence and Reciprocity, discussed earlier in this report, Michael Friedlander of Baylor College of Medicine, opined: “It is unlikely that the industry would invest that kind of money in an activity if it did not expect to receive something worthwhile in return.” Baylor College of Medicine, Department of Neuroscience Computational Psychiatry Unit, Association of American Medical Colleges, *The Scientific Basis of Influence and Reciprocity: A Symposium*, [www.aamc.org/publications](http://www.aamc.org/publications), June 12, 2007.

representative office calls, sample request fax programs, and electronic-sampling programs.” (AstraZeneca)

Industry representatives and some health care professionals and patients commented at the hearing that drug samples allow patients to start a course of treatment immediately in a prescriber’s office, to test a drug’s efficacy before incurring a large expense, to reduce patients’ health care costs, to fill gaps in insurance coverage; as well as provide opportunities for health care providers to obtain up-dated research information; and may improve adherence to a drug regimen and improve health outcomes. (*See, e.g.* Arthritis Foundation of Northern & Southern New England; Kenneth Borie, DO; Sherry Dubuque, patient; Susan Legacy, MD; Dorothy Malone-Rising, ANP; Gloria Nailor, RN; American Parkinson’s Disease Association (APDA), Vermont Chapter; PhRMA; Michael Scovner, MD; Neil Senior, MD; Michelle Thomas, patient).

A survey of 237 members of the Vermont Medical Society, provided at the hearing, reveals the following attitudes and beliefs among Vermont physicians:

- In response to the statement: “My patients benefit when I am provided with free drug samples.”
  - 51% (120 of 236 respondents), agreed or strongly agreed
  - 27% (65) disagreed or strongly disagreed
  - 22% (51) were neutral.
- In response to the statement: “I would no longer accept free drug samples if the Attorney General maintained a searchable database of the free drug samples provided to each physician.”
  - 38% (87 of 229 respondents) agreed or strongly agreed
  - 37% (85) disagreed or strongly disagreed
  - 25% (57) were neutral.

As part of a survey conducted by Pinckney of UVM College of Medicine, of 206 prescribers (out of a pool of 631), “the majority . . . agreed that samples do alter treatment plans and the majority of those with samples in their clinics believe they help patients that can’t afford their medications. . . . [T]he helpfulness of samples to determine the efficacy of a medication was not as strong of a belief.” In addition, Pinckney’s unpublished research has shown that “prescribing strategies are shifted even for patients who are not given samples, so that it increases the cost of care and leads to deviation from evidence-based practice.” (Pinckney)

## **Federal Health Care Reform Bills**

The federal health care reform legislation currently pending in Congress may incorporate regulation of free samples. Vermont may need to undertake additional statutory changes to incorporate or reconcile with federal law once it has been enacted. In the interim, this report focuses on the treatment of free samples in Vermont, considering the commentary received, the published literature, and the expressed legislative intent.

Both the pending House of Representatives and Senate bills addressing federal health care reform would require reporting of free samples of drugs (neither covers samples of medical devices). The Physician Payments Sunshine Act, contained in the House of Representatives' Affordable Health Care for America Act of 2009 (HR 3962, Subtitle D), would require manufacturers of drugs and medical devices, starting March 31, 2011, to report to HHS payments and "transfers of value" made to physicians and other health care providers. For drug samples, the bill requires reporting of recipient information and the name, number, date, and dosage units of the sample; the bill does not require that a value of the samples be provided. This information is not public; it may be made available outside HHS only for "research or legitimate business purposes pursuant to data use agreements." *Id.*, § 1451.

The Senate's Patient Protection and Affordable Care Act (HR 3590) also includes a requirement, effective April 2012, that manufacturers and distributors report to HHS the identity and quantity of drug samples requested and distributed, and the identity of the practitioners requesting and receiving the products, but not the value. These recommendations are generally consistent with the MedPAC recommendations to Congress, discussed above.

## Questions for Legislative Consideration, the Attorney General's Recommendations, and Commentary

Many who testified at the public hearing or submitted comments to the Attorney General spoke either in favor of, or opposed to, a total ban on free samples. Those comments are not extensively discussed here, because the premise of the Legislature's request for this report is that free samples will not be banned, but that it might be appropriate to require disclosure.<sup>11</sup> However, where the concerns raised by commenters arguably would apply to the question of whether disclosure of free samples should be required, those concerns have been incorporated into the discussion below.

### *Question 1: Should the distribution of free samples be reported to the Vermont Attorney General?*

*Recommendation: The distribution of free samples of drugs and medical devices should be reported to the Attorney General on an annual basis, with the timing and definitions consistent with federal regulation to the extent that that is possible while maintaining the intent of the Vermont Legislature.*

*Analysis:* Prior to the implementation of the gift ban, the Attorney General's Office has been collecting data regarding payments made by pharmaceutical companies to health care providers. This data has been helpful to the Legislature, the Attorney General, and other policy makers in understanding the facts about pharmaceutical marketing. Collecting data regarding free samples would not be unduly onerous and would result in useful information regarding the distribution of free samples to Vermont health care providers. The concerns about burden on the companies, inaccuracy in attribution of samples to an individual prescriber within a larger practice, and the potential for reduction in utilization of free samples do not appear to outweigh the benefits of the collection of improved information in an area important to health care and its attendant costs.

The Vermont Medical Society testimony was neutral on this question. (Paul Harrington, Vermont Medical Society)

---

<sup>11</sup> Two submissions advocating a ban on free samples stand out: In one, a couple wrote about their disabilities and limited income, and the necessity of choosing between heat and medicine. Although they appear to use only generic drugs, they made an appeal for Vermonters who are worse off than they: "Without some free samples from doctors, many people, who desperately need them are going to go without their medications, some may die without them." (Armand and Shirley Allen)

The second is from a researcher on the use of free prescription drug samples, who raised several concerns, among them that a significant number of drugs that were distributed as free samples later were withdrawn from the market or required to include "black box warnings." These included Vioxx, Celebrex, Zolof, and Paxil. She noted that bypassing pharmacists when prescribers provide free samples may circumvent a process intended to protect patients from adverse drug effects. (Sarah LeLeiko Cutrona, MD, University of Massachusetts Medical School; see also Community Catalyst).

## *Commentary Submitted in Opposition to Disclosure*

Commenters submitted a range of arguments against disclosure:

- Disclosure of the distribution of free samples to health care providers may give the impression of an inappropriate relationship between the manufacturer and recipient. Health care providers may be “shamed” or deterred from accepting or requesting products and this may be to the detriment of patient health. (AdvaMed; Hella Douglas, psychiatric nurse practitioner)
- “The consequence of requiring the disclosure of samples will lead to no samples at all.” (APDA, Vermont Chapter) Some prescribers will discontinue accepting samples if any form of disclosure is required, (Douglas; Scovner), or will be reluctant to accept samples. (Majorie Powell; PhRMA) Disclosure will lead to “the unintended consequence of doctors suspending their use of samples.” (Arthritis Foundation)
- There is nothing to be gained by reporting and it would decrease the use of free samples. (Neil Senior, MD)
- Physicians prescribe branded medications when they are the best choice for the patient. (Susan N. Legacy, MD; Bob Meaney, pharmaceutical industry drug representative)
- Any analysis of the reported information will not take into account the particular practice of the health care provider that is using the samples: e.g. a practitioner may use a high number of branded medications because the patient population has very complicated conditions, is very ill, or has already tried the appropriate generic medications. (Legacy)
- Disclosure creates an unnecessary antagonism with industry. The Attorney General’s Office would be sitting on a lot of information not knowing what to do with it. (Edward Terrien, MD)
- The public might draw inappropriate inferences from a public report that does not contain sufficient analysis. (Denis Barton, Bi-State Primary Care Association)
- Reporting free samples to Vermont would be administratively burdensome with no benefit beyond what is already in place at the federal level. (AstraZeneca; PhRMA)
- Increased disclosure by manufacturers will result in less availability of medications for patients of free clinics. As federal reporting has increased, free samples have decreased. (Lynn Raymond-Empey testimony, Vermont Coalition of Clinics for the Uninsured)
- The administrative burden imposed by having to track items of de minimis value might “disincent companies from continuing a beneficial practice for health care outcomes.” (AdvaMed)
- Any form of disclosure would be inaccurate because within a medical practice samples may be signed for by a practitioner who does not prescribe them or prescribed by a practitioner who did not sign for them.<sup>12</sup> (Douglas; Harrington; Legacy; PhRMA)

---

<sup>12</sup> If free samples are to be disclosed to the Attorney General, we would need to formulate a method of handling reporting by group practices. In Massachusetts, reporting is by prescriber *or* by medical practice, as both are included in the definition of “health care practitioner.” 105 Code Mass. Regs. § 970.004. With

- The disclosure legislation was detrimental legislation because it severely impacted education for doctors as most education now is provided by manufacturers. (Senior) Doctors are not all keeping up on new drugs. If reporting leads to fewer free samples, that would just make the situation worse. (Scovner)

*Commentary Submitted in Support of Disclosure*

Among the comments in support of disclosure were the following:

- “If there is a need to address, or at the very least, understand the influence of marketing on prescription practices, then why should *the bulk of promotional spending* be exempt from reporting?” (Laura Ziegler, advocate, relying on the Health Care Industry Market Update)
- “Disclosure should include not only samples delivered by drug reps but also samples delivered through e-sampling; samples distributed from a central location of a hospital or other facility; and product vouchers, coupons, or discount cards provided by or made accessible through providers.” (Adriane Fugh-Berman, MD, PharmedOut)
- Unlikely reporting would decrease the acceptance of free samples by providers, unless the doctors had to report. (Fugh-Berman testimony)
- There should be disclosure of free samples because they are part of companies’ marketing strategy. (Marcia Hams, Community Catalyst)
- Disclosure would be “a way to begin providing some objective data, instead of conflicting testimony” on “serious problems in how psychotropic drugs are being prescribed in Vermont,” “including the role played by free samples.” (Ziegler)
- Disclosure would be a good thing because it would discourage the use of samples (Fugh-Berman; Steffie Woolhandler, MD, Harvard Medical School), and the system should be “as transparent as possible.” (Borie)
- Disclosure would be “useful for tracking the amount of samples and for planning and possibly evaluating interventions,” even though disclosure alone would not likely lead to significant improvements in health care. (Pinckney)
- Disclosure would expose the fallacy that prescribers are being educated about drugs, rather than being the subject of marketing. “Mistaking marketing for education may account for over reliance on pharmaceutical interventions and reinforce the perception – which tends to dominate psychiatric practice – that drugs are the ‘mainstay of care.’” (Ziegler)

Of those commenters that did not express opposition to disclosure of free samples, some commenters focused their remarks on proposing that free samples should be banned completely. The Attorney General, after review of the testimony and written submissions, believes that for the most part, those persons supporting a ban on free samples would, in the event samples are not banned, support disclosure of free samples to

---

regard to permitted gifts or allowable expenditures, Vermont now requires the value be apportioned to the relevant prescriber or all prescribers in the practice. See Guide to Vermont’s Prescribed Products Law for FY10 Disclosures, p. 9, posted on the Attorney General’s website at [www.atg.state.vt.us](http://www.atg.state.vt.us). A comparable provision could be utilized for allocation of free samples.

the Attorney General, and most likely would support disclosure to researchers and the public as well.

***Question 2: Should reports of free samples made to the Attorney General be available to researchers?***

*Recommendation: If the Legislature acts to require data on the distribution of free samples to be reported to the Attorney General, the Attorney General should be authorized to release the data to academic researchers for analysis and public reporting, consistent with the confidential nature of the reporting, if any.*

*Analysis:* Were Vermont law changed to require reporting of free samples to the Attorney General, the Attorney General's staff could produce a rudimentary analysis of the data, similar to the type of report released on pharmaceutical marketing expenditures. The report could cover, for example, the number of free samples distributed to health care providers, the types of providers who received free samples (e.g. prescribers, hospitals or clinics, nursing homes, pharmacists, other health care providers), the number and types of free samples distributed to various types of prescribers (e.g. quantity of specific drugs to various specialists).

The Attorney General's staff, however, has neither the expertise nor the resources to conduct an in-depth analysis of the data. If the Legislature's intent is to improve our understanding of the marketing of prescribed products, as it affects costs and prescribing practices, then the value of the data collected regarding the distribution of free samples would be enhanced if it were available to researchers. For example, researchers could determine whether the provision of free samples affects prescribing patterns, the cost of health care, and health care outcomes. Analyzing these issues would require planned research studies conducted over time by academic or expert researchers, tasks not appropriate for the Attorney General's Office.

The Attorney General's Office can protect the confidentiality of information as appropriate.

*Commentary*

Few comments addressed the question of disclosure to researchers. Commentary included:

- Allowing the data to be released to professional researchers would allow researchers to analyze samples in relation to direct-to-consumer advertising, promotion to prescribers, and the utilization of drugs in public and private programs. (Community Catalyst; *see also* Sarah LeLeiko Cutrona, MD, University of Massachusetts Medical School)

- Mandatory reporting would make it possible to determine whether free samples have helped to enable inappropriate prescriptions and possible off-label marketing. (Ziegler)
- Release to researchers would increase peer learning, (Hams), and provide data for researchers that they don't have now. (Woolhandler)

***Question 3: Should reports regarding distribution of free samples be released to the public?***

*Recommendation: At this time, any public release of disclosures of the distribution of free samples should not include identification of individual recipients.*

*Analysis:* Balancing concerns regarding the possible negative consequences to doctors and patients and their health, and a possible increase in criminal activity (theft of free samples), against the potential benefits of the public release of individually identified details about the distribution of free samples, the Attorney General's recommendation is to require public release of information without individual identification of the prescriber recipients. If the Attorney General's Office initially released a report including aggregated information, after some experience with this reporting system, we would be better able to evaluate the advisability of additional public disclosure.

*Commentary Submitted in Opposition to Public Disclosure*

- Vermont Medical Society opposes public disclosure and recommends that the data already collected under the Prescription Drug Marketing Act be examined and tracked instead. (Harrington)
- Public disclosure of the recipients of free samples would deter prescribers from accepting samples with the ultimate deterioration of patient care. (Douglas; PhRMA)
- Public disclosure of where drugs samples are distributed could create a venue for criminals who seek to steal samples of particular products, (AstraZeneca; Douglas; Legacy; PhRMA), even samples that are not controlled substances. (Harrington)
- Distribution of samples is "proprietary information that is highly valued by manufacturers;" the information should be disclosed (even to the state) only in aggregate form and by type of provider. (New England Biotech Association)
- Personal view is that those most interested in reviewing information on free samples would be competing manufacturers comparing marketing activities. (Harrington)
- Public disclosure will "cast a negative light on health care professionals for accepting samples," (Douglas), and implies an impropriety on the part of the prescriber or the manufacturer. (Tremble, AdvaMed)
- There is no clear patient benefit to disclosing this information. (AstraZeneca; PhRMA)
- Disclosure would "create an economic burden on the state with no resulting benefit and possible detriment to Vermont residents," (AstraZeneca), and would not reduce health care costs. (Douglas)

*Commentary Submitted in Support of Public Disclosure*

- Disclosure allows patients to compare samples distribution among providers, may lower distribution to non-patients, and may identify gaps in the medication safety net among low income patients that can be addressed in other ways. (Community Catalyst)
- The extent of marketing through free samples should be a matter of public record because “free drug samples have many significant safety concerns. . . . and often go home in the pockets of the physicians or office staff to whom they are distributed.” (Cutrona)
- Making the data available to the public is very important. Individual health plans might want to look at its own practices and their own providers to improve policy. (Hams)
- Public disclosure is consistent with reporting of other information. People would be shocked at how much is spent on free samples. Disclosure is just the beginning of the analysis. (Ken Liberto, Vermont Association for Mental Health)
- Information released to the public should include the names of providers, together with the names and amounts of sampled drugs received. (Fugh-Berman)
- Provision for public disclosure could be limited to drugs which are not controlled substances. (Ziegler)

***Question 4: If free samples are disclosed, how should they be valued, if at all?***

*Recommendation: Any reporting to the Attorney General should include the identity, dosage, and number of units of each free sample, and the recipient’s identity. If the Legislature envisions any public disclosure of the data – whether aggregated or not – then a value should be associated with free samples; if the Legislature envisions simply that the data be made available to researchers, then a value is not necessary.*

*Analysis:* The Legislature’s concern, in discussions about this legislation, has focused on cost containment and on transparency with regard to promotion by manufacturers of prescribed products. These goals would be addressed by requiring the reporting of free samples and allowing the Attorney General and researchers to review the data. In analyzing marketing practices for prescribed products, and the impacts of such marketing on prescribing patterns, the *value* of the free samples is arguably less important than the fact that the samples were provided, and to whom. The difficulty of providing a meaningful valuation, and creating a valuation that is consistent and comparable among different sample types (including, e.g., loans of medical devices), weighs against requiring the specification of a monetary value of the free samples distributed. Perhaps for this reason, the federal recommendations (from MedPAC), and the pending federal health care reform bills, would require reporting to HHS without a specification of the value of the samples.

If the Legislature desires that the Attorney General not only collect data on free samples, but also publish an annual report or otherwise provide for public disclosure, then it may

be more important to require the manufacturers to declare the value of the samples distributed. A declaration of a monetary value would provide a common reference point by which to evaluate the magnitude of the distribution and any comparisons of companies or recipient types, better than multiple units of quantity such as milligrams, liquid ounces, pills, capsules, bandages, stents, knees, etc.

The precise method or methods of determining the value of various free samples can be resolved through legislative testimony and/or discussions among stakeholders.

#### *Commentary*

- Free samples have no value to physicians, so manufacturers would have to report value of zero. In tax circumstances there are five or six different methods of valuation. (Powell)
- Companies do not assign a value to samples they distribute and it would be a burden on them to have to report a value. (Tremble)
- Valuation is not readily available, but market value without insurance is a possibility. (Borie)
- It would be more useful to have the names and amounts of drugs distributed. Price could be reported as well, but a dollar amount would be misleading if manufacturer reports the retail value; retail value is not the actual value to the manufacturer. (Fugh-Berman)
- Vermont's free clinics report annually to the Vermont Department of Health the value and number of prescriptions, including the value of free samples provided to patients. (Coalition of Clinics). The value is obtained from on-line sources. (Raymond-Empey)
- The national figure of \$18.44 billion in value of free samples distributed in 2005 is based on retail value, as collected by IMS. So there is precedent for this valuation of free samples. (Hams)

#### ***Question 5: Should only free samples be reported to the Attorney General, or should free drug products, starter packs, and/or generics also be reported?***

*Recommendation: The distribution of generic products, if there is any by manufacturers, should not be required to be reported to the Attorney General. The Attorney General takes no position on the question of whether free drug product or starter packs should be reported.*

*Analysis:* The evidence is not as robust in support of requiring reporting of generics. Pharmaceutical companies' marketing programs and expenditures, including distribution of free samples, are usually undertaken in the promotion of brand-name, rather than generic, drugs. Congressional Budget Office, *Promotional Spending for Prescription Drugs*, Economic and Budget Issue Brief, Dec. 2, 2009, at 1. Exempting generics and free drug products from disclosure, at least if distributed to free clinics, could encourage the continued provision of those products to such clinics. Collection of data regarding

the distribution of these products would not further the same medical research purposes as data regarding the promotion of brand-name products.

Disclosure of the distribution of starter packs would reveal whether there is a shift towards greater distribution of starter packs if distribution of free drug samples to prescribers is reduced over time. However, it may not be worth the administrative costs to the manufacturers and the State of compiling and reporting that data.

### *Commentary*

At the public hearing, Lynn Raymond-Empey testified for the Vermont Coalition of Clinics for the Uninsured, representing ten Vermont free clinics “and the thousands of uninsured and underinsured Vermonters” they serve annually. The clinics operate on donated services, office space, and supplies; a state grant; and a small number of private donations.

The clinics help their patients access nearly \$600,000 of drugs annually using four strategies: 1) locating a low cost supply at a local pharmacy, 2) locating a low cost or no cost supply on line from a drug manufacturer, with the attendant eligibility guidelines and delay of 15 to 30 days, 3) providing the drugs for free, or 4) providing a voucher.

Free clinics obtain medications from pharmacy representatives, individual practitioners, and the National Association of Free Clinics’ program of free and discounted products. From the Coalition’s perspective, federal regulations “have made the donation of samples to all health care providers extremely onerous and as a result the supply of samples from providers, hospitals, etc. that used to support the free clinic programs has greatly decreased.” Only half of the ten clinics are still able to provide sample medications to their patients. One Vermont clinic had a 78% decrease in use of samples between 2005 and 2008, at the same time as they had a 33% increase in use of vouchers and a 53% increase in use of prescription assistance programs. Another clinic would have to raise an additional 37% of its cash budget were it to receive no free samples. (Coalition of Clinics) The clinics do not differentiate free samples from the other free drug products that they receive, so it is not clear what proportion of the products provided to patients at the free clinics are “free samples” as defined in this report, as distinct from “free drug product,” or drugs not being actively marketed.

Through the public hearing process, the Attorney General received no information quantifying the extent to which starter packs of drugs are used in Vermont, or whether they may affect prescribing.

## Issues Not Addressed in the Report and Recommendations

The Legislature's charge to the Attorney General focused on whether (and to what extent) disclosure of the distribution of free samples should be required. Comments on other issues of concern were submitted at the hearing and in writing. Although the Attorney General makes no recommendations on these points, the Legislature may wish to address some of these concerns through further statutory refinements.

*Other interventions to reduce detrimental effects of samples:* A number of alternatives to or additions to disclosure were suggested to reduce health care costs and improve health outcomes: Malpractice reform and insurance reform, (Douglas); creation of generic drug center, (Vermont Association for Mental Health); removing samples from clinics, stocking generic samples, using generic vouchers and sample formularies, (Pinckney, citations omitted); mandate statewide formulary for all Vermont patients, (Senior), streamline formularies and create more insurance competition. (Terrien)

*Free samples as gifts:* Some objected to disclosure requirements which "inappropriately characterize samples as a 'gift' to [health care providers] . . ." (AstraZeneca; Powell; *see also* PhRMA) If the Legislature wishes to address this, it could define free samples as an "allowable expenditure" rather than a "gift."

*Consistency with federal law:* A biotech association with 600 members emphasized the importance of consistency with federal regulations and definitions, and urged that any state requirements should make use of whatever information manufacturers are already required to report to the federal government. (New England Biotech Association)

*Prescriptions in Vermont prisons:* One commenter quoted testimony to the Correctional Oversight Committee regarding concerns about psychotropic drug prescriptions in Vermont prisons, including concerns that 75-80% of the use of antipsychotic medications is off-label. (Ziegler) At the present time the prescribed products marketing disclosure law does not allow for an easy way to separate marketing for prisoners, if there is any, from marketing for other patients.

*Disclosure requirements for health care providers:* Some commenters expressed concern about the possible burden of added administrative costs for *health care providers* to disclose the receipt of free samples. Since the current statutory provisions on disclosure apply only to manufacturers of prescribed products and we have no reason to believe that the Legislature will change that approach, we do not address this concern.

*Cost of brand name drugs:* The president of the Vermont Pharmacists Association asserts that the prices of the top 200 drugs have been raised nearly 40% over the last five years. "The focus therefore should be about legislative means to lower the cost of brand name drugs." (Marty Irons, Vermont Pharmacists Association)